Section 5 510(k) Summary

JUL 2 2 2013

Date: April 10, 2013

Submitter Information

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Name of Device

Trade name: Micro Ambulatory ECG Recorder (DiCare m1CP)
Common name: ECG Monitor
Classification name: Electrocardiograph
Production regulation: 21 CFR 870.2340
Product code: DPS

Predicate Device

HCG-801 Portable ECG Monitor (K060766, DPS, Omron Healthcare Co., Ltd.)
V-TRUST TD-2202 Portable ECG Recorder (K101569, DPS, TaiDoc Technology Corporation)

Description

The recorder is a handhold, light weight, battery-operated physiological device designed for recording ECG data. For its small size, it may be used in a clinical or non-clinical setting to record physiological signal waveforms while the patient is unattended; the device provides Real-time display function.

The device has a resolution of 24-bits with a fundamental sampling frequency of 100, 200, or 400 SPS and is stored un-compressed on a removable TF card. The sampling rate, display rate, display amplitude could be defined through control interface; meanwhile, heart rate would also be measured.

The Micro Ambulatory ECG Recorder is used for self-testing before diagnosis and is not recommended for users with implanted pacemakers or defibrillators. It works with a single lead, and has 4 testing modes:

a) Hand contact mode, place your left and right index fingers are touching the touch pads integrated on the device.
b) Leg contact mode, place your index finger on one electrode of the device and place your leg on the other electrode.
c) Chest contact mode, place your right index finger on the right touch pad of and place left touch pad on your chest.
d) Leadwire mode, using leadwires and two disposable electrodes. Paste the disposable electrodes on your body and connect them to the device through the lead wire cable.

The measurement data can be stored in the TF card, and then you can download to PC, and read the ECG by ECG Viewer software.

The device is NOT designed or intended for medical diagnosis.

Intended Use

Dimetek Micro Ambulatory ECG Recorder is intended for ECG detecting, recording and playback by adult patients who are concerned about their heart rhythm. It is used both in the clinics and home care environment.

User can choose the monitor mode and event mode to record the ECG data when feeling any heart condition occur. The device allows user to record their ECG data in TF card and playback the data for analysis by a physician or those knowledgeable about ECG morphology, rhythm, and arrhythmia.

The ECG data in TF card can be downloaded to PC, and be read by ECG viewer software.

The device is NOT designed or intended for medical diagnosis.

Summary of technological characteristics of device compared to the predicate devices (K060766 and K101569)

The Dimetek Micro Ambulatory ECG Recorder (DiCare m1CP) and the predicate devices (Omron HCG-801 Monitor & TaiDoc V-TRUST TD-2202 Portable ECG Recorder) have the similar Intended Use & Indications for Use, and similar / same technological characteristics. See Table 1.

Table 1

Technological Characteristics	Comparison Result
Intended Use & Indications for Use	similar

Operational Principle	same
Patient Population	same
Technical Parameter	similar
Performance	same
Mechanical Safety	same
Electrical Safety	same
Biocompatibility	same
EMC	same
Function	similar

Performance Data

The following practices were followed and monitored for development of the DiCare m1CP ECG Recorder:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007
- ANSI/AAMI EC38, Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems, 2007
- ANSI/AAMI EC53:1995/(R)2008 ECG cables and leadwires
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing, 2009
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

Conclusion

The ECG Recorder in this 510(k) is substantially equivalent to the predicate devices.

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 22, 2013

Dimetek Digital Medical Technologies Ltd.
c/o Mr. Ned Devine
Underwriters Laboratories, Inc
333 Pfingsten Road
Northbrook, IL 60062

Re: K131572
Trade/Device Name: Micro Ambulatory ECG Recorder
Regulation Number: 21 CFR 870.2340
Regulation Name: ECG Monitor
Regulatory Class: Class II
Product Code: DPS
Dated: May 27, 2013
Received: June 5, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free

number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use

510(k) Number: _____

Device Name: Micro Ambulatory ECG Recorder

Model: DiCare m1CP

Indications for Use

Dimetek Micro Ambulatory ECG Recorder is intended for ECG detecting, recording and playback by adult patients who are concerned about their heart rhythm. It is used both in the clinics and home care environment.
User can choose the monitor mode and event mode to record the ECG data when feeling any heart condition occur. The device allows user to record their ECG data in TF card and playback the data for analysis by a physician or those knowledgeable about ECG morphology, rhythm, and arrhythmia.
The ECG data in TF card can be downloaded to PC, and be read by ECG viewer software.
The device is NOT designed or intended for medical diagnosis.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Sub part D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.22 15:46:22 -04'00'